K100029
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Section 12: 510(k) Summary

510(k) SUMMARY

SEP 15 2010

Applicant:

Mölnlycke Health Care
5550 Peachtree Parkway
Suite 500
Norcross, GA 30092

Contact Person:

Steven Dowdley
Director of Regulatory Affairs
Tel.: 678-250-7930
Fax: 678-250-7986

Device Name:

Proprietary Name: Mepilex Border Ag Dressing
Common/Usual Name: Silver Dressing
Device Classification: Unclassified

Predicate Device Mepilex Ag Foam Dressing

Description:
Mepilex Border Ag consists of a Safetac® soft silicone wound contact layer, an absorbent polyurethane foam pad containing a silver compound and activated carbon, a layer with super absorbent polyacrylate fibres, a non woven and a vapour permeable waterproof film.

Mepilex Border Ag is a soft silicone foam dressing that absorbs exudate, maintains a moist wound healing environment and has antimicrobial properties.

Mepilex Border Ag contains silver sulfate that when in contact with fluid releases silver ions to inactivate a wide range of wound related pathogens (bacteria and fungi), shown *in vitro*. By reducing the number of micro-organisms, Mepilex Border Ag may also reduce odor.

Mepilex Border Ag has been shown to inactivate wound related pathogens up to 7 days *in vitro*.

Intended Use:
Mepilex Border Ag dressing is indicated for the management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns. Mepilex Border Ag can also be used under compression bandaging. Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.

Summary of Biocompatibility Testing:
Mepilex Border Ag was tested for cytotoxicity, sensitization and irritation and was found to be non-cytotoxic, non-irritating and non-sensitizing.

Summary of Testing for Anti-microbial Properties
Mepilex Border Ag has been shown to provide a barrier against microbial contamination and inactivates a broad range of bacteria and fungi during up to 24 hour period as demonstrated by ASTM E2149-01: "Determining antimicrobial activity of immobilized antimicrobial agents".

Mepilex Border Ag has also been shown to inactivate representative bacteria and fungi for up to 8 days, as demonstrated by ASTM E2149-01.

Mepilex Border Ag also shows a sustained release of silver over this time period. Mepilex Ag has also been shown to inactivate bacteria within 30 hours, as in demonstrated by ASTM E2149-01: "Determining antimicrobial activity of immobilized antimicrobial agents".

Conclusion:
The date provided in this 510(k) summary concludes that Mepilex Border Ag is substantially equivalent to the currently marketed Mepilex Ag Foam Dressing (cleared under K061554).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mölnlycke Health Care
% Mr. Steven Dowdley
Global Director of Regulatory Affairs
5550 Peachtree Parkway60 Middleton Avenue
North Haven, Connecticut 06473

SEP 15 2010

Re: K100029
Trade/Device Name: Mepilex® Border Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 18, 2010
Received: August 25, 2010

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Indications for Use Statement

PREMARKET NOTIFICATION

Indications for Use

510(k) Number K1000029:

Device Name: Mepilex® Border Ag

Indications for Use:

Mepilex Border Ag dressing is indicated for the management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns. Mepilex Border Ag can also be used under compression bandaging. Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K1000029